

REMARKS

This amendment is in response to the final Official Action dated September 11, 2008. Claims 1, 4, 6 and 10-13 have been amended, no claims have been canceled and no claims have been added; as such, claims 1-13 are now pending in this application. Claims 1, 4, 6, 10, 11 and 13 are independent claims. Support for the amended claims can be found in paragraphs [0070] and [0084] of the specification. Reconsideration and allowance is requested in view of the claim amendment and the following remarks.

The discloser is objected to because it contains an embedded hyperlink. To expedite prosecution, appropriate corrections have been made to the specification.

Claim Rejection under 35 U.S.C. §103(a)

Claims 1-3 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Turcott (US 6,409,675, hereinafter referred to as "Turcott '675) in view of Montserrat et al (hereinafter referred to as "Montserrat"). Applicant respectfully traverses this rejection.

Claim 1 recites: *[a]n examination apparatus for use in selecting a patient for whom an oxygen therapy is effective among patients having chronic heart failure, the apparatus comprising:*

a non-implantable biological information monitoring system, which has a unit for measuring and recording an airflow information about presence/absence or magnitude of respiratory airflow of the subject patient, and a unit for measuring and recording an electrocardiogram wave form of the subject patient having an electrode part which can be stuck on the skin of the subject patient, wherein the monitoring system is constituted such that the subject patient can move in the state having the monitoring attached on the body of the subject patient;

an analysis unit for analyzing the enhanced state of sympathetic nerves based on the measured electrocardiogram wave form; and

an output part for displaying or printing both of: (A) a transition of respiratory airflow; and (B) a transition of enhanced state of sympathetic nerves, of the subject patient during sleeping, wherein the oxygen therapy is to supply an oxygen-enriched gas for respiration of a patient.

These claimed features are not disclosed or even suggested by Turcott '675. Turcott '675 discloses a method an apparatus for monitoring the hemodynamic status of a patient. Specifically, Turcott '675 discloses an implantable monitor; in contrast the monitor in the current invention is attached on the body of a patient. Data can then be conveyed routinely and automatically, allowing more computationally demanding analysis to be done by an external device.

Turcott '675 mainly discloses an implantable monitor, in contrast the monitor in the current invention non-implantable and is attached on the body of a patient. Applicant acknowledges that Turcott '675 states that "in another embodiment the monitor is not implanted but rather is attached or worn externally by the patient daily for extended periods, such as during sleep." (Column 7, lines 25-27) However, the non-implanted monitor in Turcott '675 has ONLY the vascular plethysmography and arterial O₂ saturation sensors as recited below (Column 11, lines 41-44).

As with most of the sensors described here, the vascular plethysmography and arterial O₂ saturation sensors can be used in noninvasive, external embodiments, in contrast to incorporation in an implantable monitor.

In contrast, the current invention claims "*a non-implantable biological information monitoring system*" which is not disclosed or suggested by Turcott '675, and patients having sleep respiratory disturbances are limited to those having chronic heart failure.

Further, Turcott '675 does not disclose or even suggest "*wherein the oxygen therapy is to supply an oxygen-enriched gas for respiration of a patient.*" In fact, Turcott '675 is silent in this regard.

The Office Action states Turcott '675 "does not directly teach an electrode for measuring ECGs that are stuck on the skin of the subject," but indicates that this feature is disclosed in prior art

of Turcott '675. This is wholly inaccurate. The two generally worn external recorders are Holter recorders, which record continuously for an extended period of time. However, both of these recorders are designed for short-term use and require active patient participation. As stated in the specification, the disadvantages of prior art of Turcott '675 are overcome by Applicant's claimed invention (see paragraph [0003], [0008] and [0019]). For instance, performing home oxygen therapy to carry out the oxygen therapy at home enables continuation of oxygen therapy for a long period of time under fewer economical and social burdens and without the need for hospitalization. Further, Turcott '675 explicitly states the recorders are limited to recording the electrical activity of the heart and do not attempt to measure or quantify the hemodynamic status of the patient beyond screening for cardiac arrhythmias.

Moreover, by making the biological information system non-implantable, the biological information monitor may be attached to a patient who is movable with the monitor. A doctor may attach sensors of the recording part to the patient. The patient may go home, and biological data can be captured for 24 hours (see page 39, line 20 through page 40, line 14). Thus no large scale equipments needed for a conventional monitor, such as PSG, can be eliminated, and a doctor or his/her supporting staff may identify effectiveness of oxygen therapy applied to the patient (see page 49, lines 10-17). Thus the present invention makes it easy to check the patient while sleeping at home during his/her daily life.

On the other hand, as for implanted monitor as described in Turcott '675, the patients are limited to those having the monitor implanted. Further, the matters to be monitored are limited. Once the monitor is implanted, a doctor cannot change or adjust the location of the monitor in the cases where biological information such as breathing information or pulse information cannot be properly obtained. This is extremely inconvenient.

Further, Turcott '675 does not disclose or even suggest "[a]n examination apparatus for use in selecting a patient for whom an oxygen therapy is effective among patients having chronic heart failure." The Office Action acknowledged that Turcott '675 does not disclose or even suggest "[a]n examination apparatus for use in selecting a patient for whom an oxygen therapy is effective

among patients having chronic heart failure,” but alleges that Montserrat does. However, Montserrat does not remedy this deficiency.

Montserrat discloses Continuous Positive Airway Pressure (CPAP) is effective for sleep apnea/hypopnea syndrome. By the forgoing amendment, the subject matter is different from the disclosure of Montserrat. Furthermore, according to dictionary.com, CPAP is defined as “[a] technique of respiratory therapy for individuals breathing with or without mechanical assistance in which airway pressure is maintained above atmospheric pressure throughout the respiratory cycle by pressurization of the ventilatory circuit (visited www.dictionary.com on April 21, 2008).” In contrast, an oxygen therapy is defined on page 2 of the Specification as a therapeutic method that “is carried out in which a supplying apparatus of a gas for respiration is installed at the patient’s home; an oxygen-enriched gas supplied by this supplying apparatus of a gas for respiration is introduced to the vicinity of nasal cavity of the patient using a tubing member referred to as cannula; and the patient inhales the gas. This type of oxygen therapy is also referred to as “home oxygen therapy” (HOT). According to these definitions above, CPAP is completely different from oxygen therapy. Therefore, Montserrat does not teach or suggest the use of oxygen therapy and its effectiveness of the purpose of treating patients with SAHS.

Paragraph 10 of the Office Action alleges Applicant has not incorporated the difference of CPAP verses HOT. With the claim amendment above, Applicant has clarified the difference.

Since even a combination of the relied upon references would still fail to yield the claimed invention, Applicant submits that a prima facie case of obviousness for claim 1 has not been presented. Applicant also notes that the offered combination appears to be a failed attempt to reconstruct the claimed invention in hindsight, as there is no basis to combine the implantable hemodynamic monitor of Turcott ‘675 with the CPAP treatment of Montserrat.

Furthermore, at least for the reason disclosed above, claims 2-3 overcome the combination of Turcott ‘675 and Montserrat because they depend on independent claims 1.

Accordingly, Applicant respectfully requests that the rejection of the claims under 35 U.S.C. § 103(a) be withdrawn.

Claims 4-13 are rejected under 35 U.S.C. §103(a) as being unpatentable over Turcott '675 and Montserrat and further in view of Thomas et al. (U.S. Pub. No. 2004/0144383, hereinafter referred to as "Thomas '383"). Applicant respectfully traverses this rejection.

Claims 4-13 depend from and thus incorporate the features of independent claim 1, which are neither disclosed nor suggested by Turcott '675 in view Montserrat, for the reasons stated above.

Thomas '383 does not remedy the deficiencies of Turcott '675 or Montserrat, as the various features recited above are also absent from Thomas '383. For example, Applicant's 383 claimed features of "*[a]n examination apparatus for use in selecting a patient for whom an oxygen therapy is effective among patients having chronic heart failure,*" or "*a non-implantable biological information monitoring system, which has a unit for measuring and recording an airflow information about presence/absence or magnitude of respiratory airflow of the subject patient, and a unit for measuring and recording an electrocardiogram wave form of the subject patient having an electrode part which can be stuck on the skin of the subject patient, wherein the monitoring system is constituted such that the subject patient can move in the state having the monitoring attached on the body of the subject patient,*" are neither disclosed nor suggested by Thomas '383.

Thomas '383 discloses a gas system for supplying pressurized air for stabilizing breathing of target patients or users and a control processor. The control processor of Thomas '383 may be responsive to patient state information including ECG and EKG signals. Applicant respectfully submits that is has nothing to do with the features claimed by the Applicant, which provides an apparatus for examining patients having chronic heart failure.

The three-way combination thus similarly fails to present a prima facie case of obviousness, as the combination still fails to collectively disclose the features recited in the independent claim, let alone the additional features recited in dependant claims 4-13.

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Docket No.: TEI-0135

Accordingly, Applicant respectfully requests that the rejection of claims 4-13 under 35 U.S.C. § 103(a) as being anticipated over being unpatentable over Turcott '675 and Montserrat and further in view of Thomas'383 be withdrawn.

In view of the above amendment and remarks, applicant believes the pending application is in condition for allowance.

This response is believed to be a complete response to the Office Action. However, Applicant reserves the right to set forth further arguments supporting the patentability of their claims, including the separate patentability of the dependent claims not explicitly addressed herein, in future papers. Further, for any instances in which the Examiner took Official Notice in the Office Action, Applicant expressly does not acquiesce to the taking of Official Notice, and respectfully request that the Examiner provide an affidavit to support the Official Notice taken in the next Office Action, as required by 37 CFR 1.104(d)(2) and MPEP § 2144.03.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 18-0013, under Order No. TEI-0135 from which the undersigned is authorized to draw.

Dated: January 6, 2009

Respectfully submitted,

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